EXHIBIT C

SCOTT SERELS, M.D. –EXPERT REPORT

I. QUALIFICATIONS AND EXPERIENCE

1. A curriculum vitae providing the details of my education, experience and training in medicine, including in the field of urology, is attached as Exhibit 1.

2. I received my Bachelor of Arts degrees in biology and economics magna cum laude from Brandeis University in 1988. I received my medical degree from New York University School of Medicine in 1992. I then completed two years of surgical residency, and four years of urologic residency at the Albert Einstein College of Medicine and Montefiore Medical Center. During my urologic residency, I completed rotations in urologic oncology and female urology at Memorial Sloan Kettering and UCLA, respectively. I then went to the Cleveland Clinic Foundation to serve as a clinical associate specializing in female urology, urodynamics and neurourology with Dr. Rodney Appell in 1998-1999. It was at this time that I also completed my fellowship training.

3. I have been an investigator for many clinical trials involving pharmacologic agents, pubovaginal slings as well as mesh for pelvic floor prolapse.

4. I currently practice medicine at the Bladder Control Center of Norwalk, where I am the director of daily operations involving urodynamics, female urology and neurourology. I was board certified in urology in 2001, and American Board of Urology recertified in 2009. I became board certified in female pelvic medicine and reconstructive surgery in 2013.

5. I received the Samuel Soifer Memorial Award for Excellence in Urology in May 1992, the Montefiore Medical Center Resident Recognition Award in May 1995, and the Scallon Surgical Award for surgical innovators in May 2001. I have lectured on pelvic prolapse and incontinence throughout the United States and in Europe.

6. I am a clinical faculty member at the Frank H. Netter School of Medicine at Quinnipiac University, where I also serve as a member of the faculty counsel. Additionally, I am a member of the clinical faculty at the University of Vermont Medical School. I am also the Urogynecology Section Head at Norwalk Hospital in Norwalk, Connecticut. I have authored approximately 100 peer-reviewed publications, presentations and abstracts in the fields of urology and urogynecology.

7. Presently, I am a very active surgeon. I see at least 100 patients a week. Operatively, I have done 1000's of pubovaginal slings using all sorts of approaches. I am experienced in the retropubic, obturator, and single incision techniques. I helped develop and introduce the obturator approach in the United States. Additionally, I was instrumental in helping to develop several of the single incision slings that are on the market currently. As having considerable knowledge on the use of slings, I have published and taught extensively on the use of slings. Throughout the years, I have been involved in many research projects involving incontinence both investigator initiated and corporate sponsored.

8. My opinions are based on my vast experience as a researcher and clinician as well as the knowledge of the literature. I have considerable influence in the medical community because of this vast experience. Additionally, I have extensive experience teaching residents and fellows on the risks and benefits of surgical treatment for stress urinary incontinence and pelvic organ prolapse, including training on the Instructions for Use (IFU).

9. In summary, in my opinions discussed below, the TVT's design and material is reasonably safe for its intended use and the Instructions for Use adequately and appropriately warns physicians trained in the surgical treatment of stress urinary incontinence of the potential adverse reactions associated with the device.

II. STRESS URINARY INCONTINENCE

A. Background:

Incontinence is the involuntary loss of urine. This condition can affect both men and women. The prevalence increases with age. Stress urinary incontinence (SUI) accounts for 15-80% of the incontinence seen in women. The loss of urine is a considerably debilitating condition for those affected. It has a considerable impact on one's quality of life. Individuals are more likely to avoid social or active situations. They wear clothing to hide their leakage, which would either be by using dark clothing to hide staining or baggy clothing to hide incontinent pads/diapers. Affected individuals may have difficulty in their work environment due to concerns of embarrassment.

The risk factors for SUI would include older age, obesity, previous pelvic surgery, and pelvic organ prolapse. The most common reason for SUI however is delivering children vaginally. The more vaginal deliveries impart a higher risk of developing SUI. In the article by Rortveit et al that appeared in the New England Journal of Medicine, The prevalence of any incontinence was 10.1 percent in the nulliparous group; age-standardized prevalence's were 15.9 percent in the cesarean-section group and 21.0 percent in the vaginal-delivery group.

The diagnosis for incontinence in general is made by doing a careful physical exam, which is specifically concerned with the pelvic anatomy, and a thorough history addressing questions related to voiding. These questions would include frequency of urination in the day and night as well as urgency to void and leakage with increase in abdominal pressure.

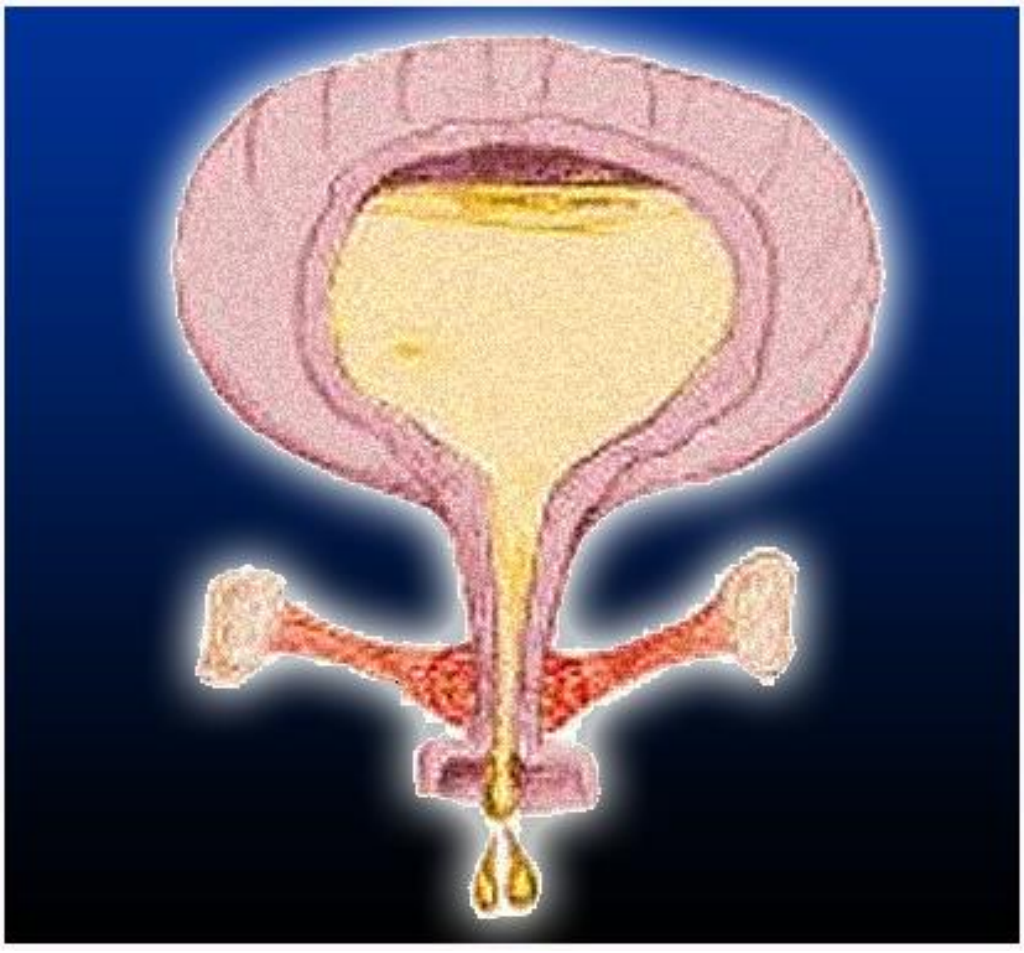
B. Definition:

Stress Urinary Incontinence (SUI) is a condition that affects mostly women. It is defined as the involuntary loss of urine with increases of intraabdominal pressure. This condition in turn

translates to leakage of urine with laughing, coughing, jumping, exercise, etc. The most common reason for developing SUI is having had children especially if they were delivered vaginally. Other factors that may contribute are age, pelvic surgery, and menopausal status.

C. Etiology/Anatomy:

To understand the cause of SUI, one must understand the anatomy. Everyone has a bladder and a channel that goes from the bladder to the skin. This channel is called the urethra. At the mid-portion of the urethra is a muscle. When this muscle becomes weakened, one develops SUI.



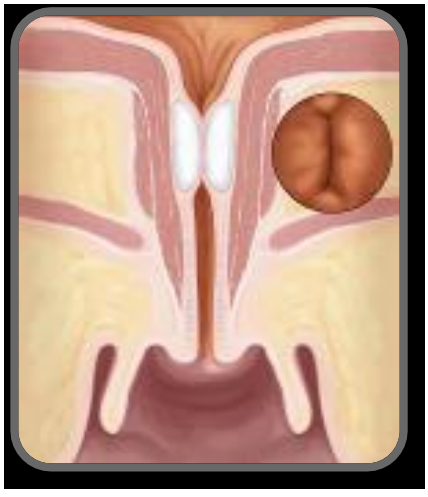
D. Treatment Options:

1. Many patients are forced to use absorbent products to catch the urine. This is a very costly option as most of the products are disposable. Also, many patients suffer skin breakdown and/or infections from their use.

2. There have been many medications tried for the treatment of SUI, but none have proven to be effective overtime. Thus, there is currently no FDA approved medication to treat SUI.

3. Physical therapy and biofeedback are options that have been met with modest success.

4. Injectable agents were used to bulk up the area of the urethra where the muscle has failed, and this was also met with limited success. The commonly used agent was collagen, which has since been voluntarily removed from the market. Other injectable agents both synthetic and biological are currently available. Most of these agents take some finesse to inject and may take more than one injection to achieve success. Furthermore, the injections may wear off and need to be repeated. Thus, Injection therapy has not become the standard of care.



E. Surgical treatments:

Surgeons have been treating SUI for approximately a century. The first surgical paper described the Kelly plication. The goal of all surgical therapies is to achieve dryness that has a sustainable effect. The Kelly plication involved a vaginal incision, which was under the urethra and used to bunch up the tissue in this area to resupport the urethra. Unfortunately, the long-term results were not very good. The 5-year success rate was only 37%, which is far from satisfactory.

In 1949, the Marshal Marchetti Krantz (MMK) procedure was described to ressuport the urethra via an abdominal approach. This procedure was initially done through an abdominal incision and later laparascopically. The 5-year cure rates were around 86% but the procedure has been used much less often due to the abdominal approach and the possibility of adverse events. There were high rates of osteitis pubis and urethral vaginal fistulas as well as other complications, which in some studies exceeded 20%.

A variation of the MMK is the Burch procedure. Both procedures require "direct access" to the tissues surrounding the bladder and urethra and are deemed "major" surgical cases that involve an abdominal incision and wide vaginal dissection. This extensive surgery is associated with a significant risk of wound complications, bleeding, and genitourinary tract injury including damage to the ureter, bladder, and urethra (Stanton 1985). Urinary tract injuries have been reported to occur in 6.3% of pubovaginal sling procedures (Summitt, 1992) and in up to 9% of Burch procedures (Stevenson 1999). The 2012 AUA Guidelines Appendices and the SGS 2014 Meta-Analysis also provide detailed complication rates for the Burch and Autologous fascial slings compared to synthetic midurethral slings. Median surgical times are typically in excess of

2 hours, hospital stay averages 2-3 days, and prolonged catheter drainage is usually required. Many patients could not commit to that lengthy recuperation period.

The concept was to place sutures abdominally on either side of the urethra and then anchor them a bit laterally to the MMK procedure. These procedures have also fallen out of favor due to adverse events. There was a risk of bleeding, voiding dysfunction and bladder injuries. De novo urgency and obstructive voiding has been described in up to one third of the patients. Additionally, there have been reported rates as high as 37% in terms of the development of pelvic organ prolapse. These sequelae could result in further surgical intervention.

In an effort to avoid an abdominal incision, Needle suspension procedures were developed. In these procedures, a needle was passed from the suprapubic area to the vaginal area so as to re-support the tissue on either side of the urethra. The support of the tissue was done by a permanent suture with or without an attached to a pledget. Dr. Pereyra was the first to describe his technique in 1959. The subjective cure rates were less than 50% after 2 years. Complications included detrusor instability, voiding dysfunction and infection. Dr. Stamey and Dr. Raz further modified this procedure. However, the success rates long term were not reproducible and the procedures were virtually abandoned.

The Vesica procedure was developed in the 1990's. It was an attempt to commercialize and standardize the needle suspension. It was a kit that came with a disposable need to pass from the abdominal to the vaginal area. It also used bone anchors to fixate the sutures into the pubic bone. This procedure like its predecessors had low cure rates and unacceptable complications.

F. Pubovaginal Slings: The gold standard

Pubovaginal slings have been used for decades. Dr. Van Giordano, described the first sling in 1942. Traditionally, the sling referred to a suspensory that was placed under the urethra and brought through the retropubic space and anchored on either side of the midline. Originally, It was performed using autologous tissue as the suspensory. Dr. Van Giordano used gracilis muscle and then rectus fascia and fascia lata were popularized in the 1940's. Since this original concept, there have been many materials used for the sling, and there have been many different anchoring approaches. These anchoring approaches included using sutures and bone anchors. The materials involved attempted use of animal tissues such as bovine from the cow and porcine from the pig. Cadaveric tissues were also used as well as various synthetic materials. One material in particular was known as protegen, which was a woven polyester material. Protegen was introduced into the market in 1997 and taken off the market in 1999.

It wasn't until the mid to late 1990's that the use of slings expanded. This expansion was due in part to the use of polypropylene mesh. It was Ulmsten and Petros who proved to the medical community that one could correct SUI by using a piece of polypropylene mesh. Mid-urethral slings have revolutionized the surgical approach to SUI management.

The design of the tension free vaginal tapes incorporated several design features:

1. To avoid the need for a major abdominal incision and use the vagina as the primary route of surgical access.

2. Introduce a stable hammock of support at the level of the mid-urethra and not the bladder neck.

3. Provide urethral closure only during episodes of increased intra-abdominal stress and not at rest, thereby reducing the risks of voiding dysfunction.

4. Use a sling material that was safe, durable, and did not require harvesting of native tissue.

5. Design a system that required minimal tissue dissection, thereby maximally preserving the nerves and surrounding supportive tissue.

6. Design a procedure and technique that is highly reliable and reproducible.

Additionally, at the same time the synthetic sling became available, there was an enormous effort by device companies to educate the physicians. This education did not only include Urologists who were the main surgeon providing slings to their patients but it included Gynecologists. This initially involved using transvaginal tape through the retropubic space. The early results of Ulmsten showed cure rates of 86% and improvement rates of 11%. There were initially reports of bladder injury rates of 1-6% and mesh erosion rates of 1-2%. Although this worked well, there still was the potential for adverse events involving the bowel, bladder, and vascular structures]. Most of these complications were due to the use of trocars in the retropubic space.

The transobturator sling was an evolutionary advancement, which attempted to preserve the high success rates of retropubic polypropylene slings while minimizing the chance of surgical complications. This sling in theory eliminated the chance of bowel injury and significantly reduced the chance of bladder injury. It was first introduced in 2001 by Delorme. There were many variations of the obturator sling used with success rates objectively and subjectively in the 90% range. However, it still proved to possibly cause vascular injury to the obturator vessels or nerve injury to the obturator nerve. These patients were also at risk of groin pain either from muscular or tendon injury or perhaps neurologic irritation. Also, the medical community was looking for a sling that was the least invasive with high success rates and

minimal chance of complications. In response to these desires, a polypropylene sling using a single vaginal incision was created.

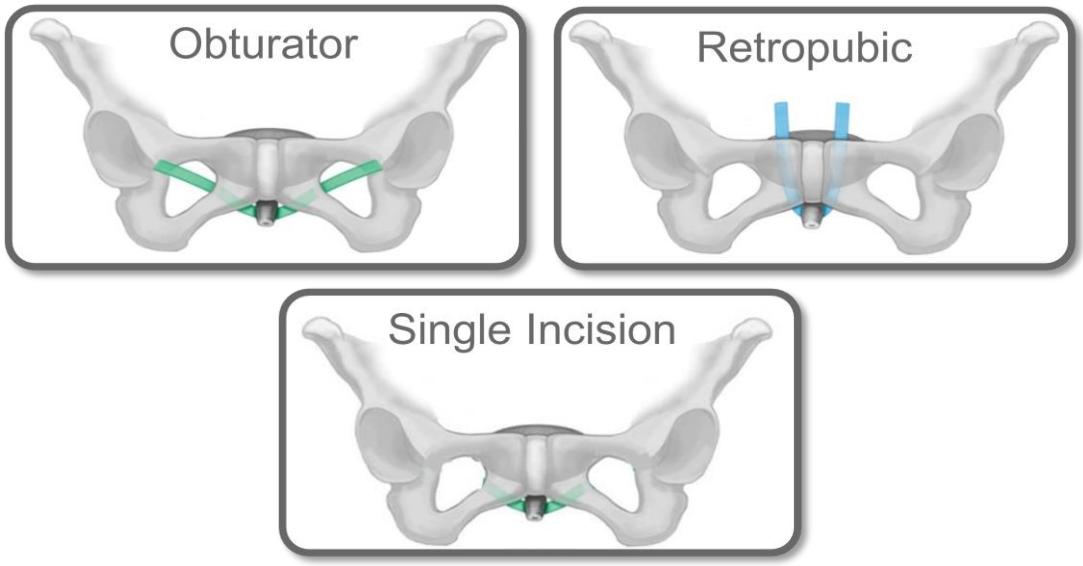
The single incision sling (SIS) technique enables the user to place a piece of polypropylene mesh through a single vaginal incision. The idea of a SIS was first used approximately 7 years ago. The sling material varied in lengths from 8-9 cm. Some of these slings used fixation anchors while others relied more on scaring to provide fixation. Throughout the years, there were even variable length slings developed. The techniques for placement of many of the previous single incision slings were not consistently uniform. As a result, the early data for the single incision slings were not always comparable to those seen with transobturator and retropubic slings. However, the most recent retrospective and prospective studies on the use of second-generation single incision sling systems have demonstrated relatively high success rates with minimal morbidity.

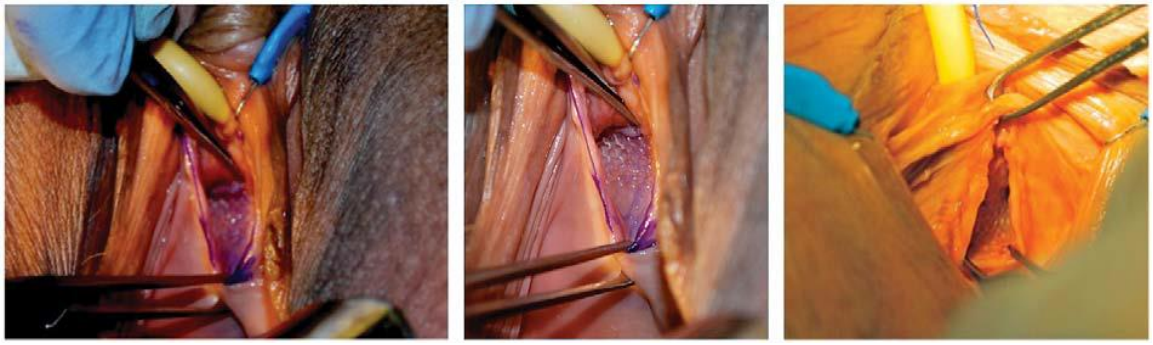
G. Surgical Technique:

To enhance the understanding of the Sling, it is important to understand how it is placed. The description below provides the generalized technique for the placement of the single incision sling. The reproducibility and "teachability" of the procedure, broken down into a clear series of surgical steps, was demonstrated through a systematic training program of all surgeons in Finland who wished to use the TVT. Results of this study, which detailed outcomes of 1455 patients, demonstrated how a standardized training program can achieve optimal outcomes (Kuuva, 2002).

Prior to the surgery, intravenous antibiotics are administered. The patient is then given local, general, or regional anesthesia at the discretion of the surgeon in combination with the anesthesiologist. A dorsal lithotomy position is then achieved to facilitate surgery. A foley is

inserted to empty the bladder. A 1-2cm anterior vaginal wall incision is made at the level of the midurethra. The dissection is then carried out laterally to the level of the inferior pubic rami on either side using blunt and sharp dissection. This surgical preparation provides a pathway for the delivery of the sling arms. The polypropylene mesh is placed using an introducer, which is inserted into the dissected pathway and used to pass the sling behind the pubic ramus... This placement of the sling is repeated similarly on the opposite side. The polypropylene mesh sling is then brought to rest under the midurethra in a tensionless fashion. The goal of the surgeon is to visually see the periurethral tissue "pillowing" through the mesh material with a potential space existing between the sling and urethra such that a small instrument could easily be inserted. Cystoscopy is performed to ensure the bladder, urethra, and ureters are not compromised. The vaginal incision and skin incisions (if applicable) are then closed with a running absorbable suture.





Placement of mid-urethral slings to alleviate stress urinary incontinence using the (a) retropubic; (b) transobturator;(c) single incision technique.

H. FDA Controversy:

In 2011, the FDA started to investigate the use of urogynecologic surgical mesh in the setting of pelvic organ prolapse. It then issued a safety and efficacy update, which did not include slings. It was also going to evaluate the use of mesh for sling procedures at a later time. In 2013, the FDA did conclude that clinical trials did support the safety and effectiveness of slings. Subsequently, The AUA, SUFU, And AUGS have issued position statements supporting the use of slings in the female population.

I. Opinion of Sling surgery:

1. The use of synthetic Pubovaginal has created a reproducible way of correcting SUI. Polypropylene as a sling material has been a wonderful advancement. Prior to using polypropylene, there were many materials that were tried. These materials included autologous fascia lata, autologous rectus fascia, bovine, porcine, vaginal wall, and woven polyester. It was an evolutionary process to find a good working material that could correct a very serious problem easily. It was to the credit of many physicians, engineers, and supportive corporations that we can now offer our patients a successful procedure. A synthetic sling procedure can now be done in minutes under local anesthesia in an outpatient setting. There

have been over 3 million slings placed with over 2000 studies performed. It has been deemed safe and effective by most of the governing physician bodies, and I concur with their conclusions.

2. Controversy with Slings: All of the controversy with polypropylene slings started with the FDA and its review of polypropylene mesh use for vaginal vault prolapse. The FDA noticed a trend toward complications using large pieces of mesh in the vaginal area and attributed this to the nature of the material. The sling was investigated only because it was made out of a similar material. This same polypropylene material is also used to make abdominal sutures for the last 40 years and abdominal hernia mesh for the last 30 years. It is my contention that polypropylene mesh slings are a wonderful advancement that needs to be integral part of our treatment.

III. CONCLUSION:

I have an intimate understanding of what the reasonably prudent pelvic floor surgeon should know about the risks and benefits of pelvic floor procedures, the adequacy of the warnings in IFUs, the management of mesh complications, and the well-known risks that are associated with any pelvic floor surgery. It is well known by all pelvic floor surgeons that any surgery for stress urinary incontinence or pelvic organ prolapse, with or without the use of mesh, can potentially cause complications that can be temporary or permanent, including but not limited to: pelvic pain, dyspareunia (pain with sexual intercourse), scarring, vaginal narrowing, leg/groin pain, urinary retention and other voiding problems. There will always be complications with any surgery. It is important to note that these complications occur in all procedures for stress incontinence and are not unique to mid-urethral slings. In fact, when

complications are directly compared, the TVT appears safer than either the Burch procedure or pubovaginal sling.

Several potential problems with polypropylene mesh have recently been hypothesized. These issues are the potential for carcinogenesis from polypropylene, the degradation of mesh as causing clinical sequelae, as well as the concerns with how the mesh is processed and cut during production.

Type I mesh is monofilament and manufactured with a pore size greater than 75 microns. The Prolene TVT mesh is considered to be an Amid Type 1 mesh, and is commonly referred to as large-pore and lightweight mesh. The initial TVT trials with Prolene mesh by Ulmsten, showed no adverse reaction. Specifically, there was no indication of unacceptable rates of mesh infection, rejection, host tissue reaction, or impaired healing.

There is likewise no clinical significance to claims of alleged particle loss and mesh degradation over time. Such claims are not supported by any level 1 evidence, nor have I experienced any complications attributable to alleged particle loss or degradation in my 20 years of clinical practice.

Ethicon still sells both mechanically cut and laser cut TVT in order to satisfy surgeon preferences. . There has been rigorous clinical data from implants prepared using the 2 different techniques. There has been robust opportunity to assess for any difference in outcomes. None have been observed. Overall, this theoretical risk has led to no measurable clinical effect or risk.

Plaintiffs' experts have also suggested that TVT implantation results in carcinogenic effects or adverse systemic effects associated with alleged cytotoxicity. These claims are not accompanied by any methodologically sound or scientific analysis, and is completely lacking in clinical significance.

Polypropylene has been used as a surgical suture for approximately 40 years and as a surgical hernia mesh for approximately 30 years. These concerns have not proven true with these uses. There has not been any meaningful level I scientific literature to support any of the above-mentioned concerns for abdominal mesh or any other form of polypropylene . In addition, I have not seen any level I scientific study to prove that polypropylene used vaginally will results in any of the above occurrence. Furthermore, over the last 20 years of clinical practice I have not seen any evidence of to support these findings.. The choice of a macroporous, monofilament, polypropylene mesh tape as the most suitable material for use in mid-urethral slings is substantiated by strong clinical data.

There is always the possibility of human error or other technical considerations that may play a role in the use of polypropylene products. The material science of TVT mesh does prove that if undue tension is placed on the mesh material, and it is significantly stretched, then the sides of the sling can curl in, and instead of a flat piece of mesh it can assume the appearance of a “rope”. This is only possible if after the tape is placed, and the plastic sheaths are removed, significant tension is applied to the ends of the exiting sling in order to tighten the mesh. This technique is clearly contrary to what is outlined in the surgical steps of the IFU.

It has also become quite popular to blame one’s incontinence procedure for many ailments that are unrelated. It is also the legal system and the allure of compensation that can sometimes bring out the worst in people. It is this type of temptation that destroys the evolutionary advancements in the treatment of stress urinary incontinence. Without the continued use of the polypropylene mesh sling, it would set back the treatment of female SUI by at least two decades.